



UNITED STATES PATENT AND TRADEMARK OFFICE

MAR 20 2009

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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Patrick Sage
The Firm of Hueschen and Sage
Seventh Floor, Kalamazoo Building
107 West Michigan Ave.
Kalamazoo, MI 49007

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,061,703

Dear Mr Sage:

The USPTO is in receipt of your letter of March 13, 2009 waiving the reconsideration period set forth in the Notice of Final mailed March 3, 2009. In accordance with the waiver, a certificate of extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 5,061,703 for a period of 5 years. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products).

Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website:

<http://www.fda.gov/opacom/morechoices/fdaforms/default.html>

(<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till

Legal Advisor

Office of Patent Legal Administration

Office of the Deputy Commissioner

for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave
Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: NAMENDA® (memantine
hydrochloride)
FDA Docket No.: 2006E-0332

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

(12)

CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : 5,061,703
(45) ISSUED : October 29, 1991
(75) INVENTOR : Joachim Bormann, et al.
(73) PATENT OWNER : Merz Pharma GmbH & Co. KGaA
(95) PRODUCT : NAMENDA® (memantine hydrochloride)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 5,061,703 based upon the regulatory review of the product NAMENDA® (memantine hydrochloride) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94)

5 years

from April 11, 2010, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).

I have caused the seal of the United States Patent and Trademark Office to be affixed this 18th day of March 2009.

JOHN J. DOLL

Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

